Sensory Perceptions of Nicotine Replacement Therapy between Menthol and Nonmenthol Cigarette Smokers

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Introduction

The prevalence of smoking in the United States has decreased in percentage from 42.4% to 19.3% from 1965 to 2010 due in part to the number of people who have quit smoking. There are many different factors that have worked together to help bring down this statistic including, media campaigns, prices on tobacco, and different counseling and cessation products used by consumers and health care providers. Although the prevalence of smoking in the United States has decreased significantly, there is still a high interest in smokers who would like to quit and have not yet done so successfully (Malarcher, Dubes, Shaw, Babb & Kaufman, 2011).

In a 2010 National Health Interview Survey interest in quitting was highest amongst non-Hispanic black smokers at 75.6%, followed by non-Hispanic white smokers at 69.1%. In spite of the fact that non-Hispanic black smokers showed the most interest in quitting smoking, cessation was more likely among non-Hispanic whites at 6.0% than among non-Hispanic blacks at 3.3% (Malarcher et al., 2011). The overall finding concluded that whereas non-Hispanic black smokers had a higher interest in quitting and past year quit attempts than non-Hispanic whites, they had a lower prevalence of recent smoking cessation. The survey showed that possible contributors to this disparity in smoking cessation could include non-Hispanic blacks' lower utilization of evidence based cessation treatment and their high rates of menthol cigarette use. Data from the survey showed that 76.7% of non-Hispanic blacks smoked menthol cigarettes versus 23.6% of non-Hispanic whites (Malarcher et al., 2011).

Menthol is present in 90% of all tobacco products, although the concentration in tobacco products varies according to the product characteristics and flavor desired (Anderson, 2011). In 2008 more than one third of Americans who smoked in the past month who were 12 years of age and older reported smoking menthol cigarettes, a rate that equates to over 10 million menthol

smoker users in the United States. The highest percentage of these smokers falls in the categories of non-Hispanic black smokers (82.6%) and young smokers (44.8%) (Levy, Blackman, Tauras, Chaloupka, Villanti, Niaura, Vallone & Abrams, 2011). Although few studies have explored the impact of menthol cigarette use on smoking cessation products in large population based studies, research suggests that smoking menthol cigarettes negatively impacts smoking cessation among adults (Levy et al., 2011).

The purpose of this study was to evaluate the relationship between menthol cigarette use and cessation rates through usage of nicotine replacement therapy (NRT) versus non-menthol cigarette users. The following research questions will be addressed:

1. Are menthol cigarette users more likely to quit using NRT treatment than non-menthol cigarette users using NRT treatment in a two-week study?
2. What is the relationship between cigarette smoking and NRT usage regarding sensory perception in the categories of liking, satisfaction and sensation strength?
3. Is there a difference in the sensory perception of liking, satisfaction and sensation strength between menthol and non-menthol cigarette smokers?

Review of Literature

Sensory perception of liking, satisfaction and sensation strength

Although a great deal is known about menthol as a flavoring agent in food and confectious products, less is known about the particular sensory properties of menthol cigarette smoke. The concentration of menthol in tobacco products varies according to the desired flavor and product characteristics, but is present in 90% of all tobacco products whether these products are marketed as mentholated or not (Anderson, 2011). Owing to its physiological effects, menthol contributes to the sensory qualities of the smoke and affects smoking topography and cigarette preference (Yerger & McCandless, 2011). This leads into the research question: Is there a difference in the sensory perception of liking, satisfaction and sensation strength between menthol and non-mentholated cigarette smokers.

Menthol can produce a number of effects when applied topically to the nose, mouth and throat. These include the sensation of cooling and sensory irritation. Because the topical application of menthol to the mucosal surfaces of the mouth and tongue can, in some circumstances, reduce the sensory irritation induced by topical applications of nicotine, a number of researchers have claimed that menthol in cigarette smoke may reduce the levels of sensory irritation in the mouth and throat induced by cigarette smoke (Ahijevych & Garrett, 2004).

Findings from one research study suggested that high menthol concentrations in products produce greater intensities of ‘cooling’ and ‘strength’ of menthol taste than the low menthol concentration products. After conducting the study and collecting the data, a General Linear Model approach was used to compare smokers’ mouth level exposure to tar and nicotine and smokers’ sensory magnitude scores (Ashley, Dixon, Sisodiya & Prasad, 2012). The results

indicated that there was no significant difference in magnitude of mouth and throat irritation between non-menthol and mentholated products when the products were smoked by Japanese and Polish regular menthol smokers, yet a perceived mouth and throat irritation difference was noted in the non-menthol and menthol products in the occasional menthol smoker groups. The data overall does not support the notion of a menthol induced increase in mouth level exposure to tar and nicotine or menthol induced reduction in the level of mouth and throat irritation produced by cigarette smoke (Ashley et al., 2012). This study shows that the amount of menthol used in the cigarette does not affect the sensations of cooling or strength of taste, and even low levels used in cigarettes can cause these positive sensations. The positive sensation can then cause an increase in prolonged usage, as there is a decrease in the level of irritation normally found in non-mentholated cigarettes (Ashley et al, 2012).

Smoking cigarettes is meant to be an enjoyable experience, one that tobacco companies have worked extensively to make pleasurable for many different consumers. Tobacco companies' understanding of how menthol works in regards to the body's airway and sensory perception of the chemical helps the companies to create cigarettes that are less irritating and marketable to younger and inexperienced smokers. In a snowball sampling design, conducted by Yerger, 2011 the Legacy Tobacco Documents Library was searched using keywords related to nicotine, menthol, dependence and addiction. A final collection of 309 documents was analyzed, of which 50 were represented and cited in their paper. The findings showed that menthol's cooling effect is a result of a chemical action that occurs near nerve endings that are associated with the sensation of cold. When menthol is added to cigarettes and smoked, this cooling sensation is experienced in the throat (Yerger, 2011). The cooling sensation of menthol and its physiological effects are dose sensitive and increasing the amount of menthol beyond a certain

point does not result in a greater degree of cooling, but could increase other sensations such as tingling, stinging or burning. Small concentrations of menthol are more effective than large quantities, which can depress receptor stimulation (Yerger, 2011). Thorough review of the documents cited showed that menthol has a pronounced effect in nicotine-derived impact. The study concluded that cigarettes without nicotine were preferred more when menthol was added (Yerger, 2011). In a 1979 Roper report, it was stated that menthol compensated for the reduced taste in 'light cigarettes,' which would have been less satisfying to smokers. In 1989, Phillip Morris established its 'Trigeminal Panel', which showed that menthol produced some nicotine-like central nervous system and subjective effects in humans, and could be a partial replacement for nicotine. The evidence presented in the article, *Menthol's potential effects on nicotine dependence: a tobacco industry perspective,* written by Yerger, 2011 showed that menthol is not just an ingredient added to cigarettes to make them taste a certain way. Menthol even in low levels masks the harshness of tobacco and alleviates the irritation associated with nicotine, as well as producing some nicotine-like sensory effects.

Besides its cooling properties, the influence of menthol on the effects of smoke-delivered nicotine is unknown. In a double blind study conducted by Pickworth, Moolchan, Berlin and Murty, 2001 the interaction between menthol and nicotine was studied to determine the influence on the physiologic and subjective effects of smoking. In this study there were 36 volunteers who were in good health, had been a smoker for at least two years, and smoked 15 or more cigarettes per day. Subjects were separated into two groups based on their usual cigarette preference. The menthol group was composed of 13 men and 5 women, of which 17 were African American and 1 was Caucasian. In the nonmenthol group, there were 14 men and 4 women of which 3 were African American and 15 were Caucasian.

This experimental design leads to ethnic differences in group composition. Four research cigarettes were made, nonmenthol high yield, menthol high yield, nonmenthol low yield and menthol low yield (low yield cigarettes contained no nicotine). Before and after each cigarette was smoked, systolic and diastolic blood pressure and heart rate were measured. After each cigarette, subjects completed the Duke Sensory Questionnaire and a Cigarette Evaluation Scale. Each subject smoked a research low and high yield menthol and nonmenthol cigarette. The evidence showed that cigarettes that contained nicotine increased heart rate and systolic and diastolic blood pressure compared to the low yield nicotine cigarettes (Pickworth et al., 2001). Furthermore, the evidence showed that the addition of menthol did not significantly affect cardiovascular parameters indicating that mentholation does not significantly change the effects of smoking cigarettes that deliver average and higher amounts of nicotine. The effects of the cigarettes were assessed on subjective measures of satisfaction, strength, craving relief, sensation, psychological reward and negative effects. The trend observed was that nicotine delivery, not menthol flavoring determined subjective ratings of strength and sensory impact (Pickworth et al., 2001). Thus the study concludes that nicotine content, not mentholation was the factor in determining the physiologic and subjective effects of smoking.

Menthol usage in cigarettes is promoted by the tobacco industry because of its perceived sensory benefits. In an article written by Kreslake, Wayne and Connolly, 2008 two unique types of menthol smokers emerged from analyzing internal tobacco industry documents: those who can tolerate the harshness and irritation associated with nonmenthol cigarettes and those who seek out the specific menthol flavor and associated physical sensation. In this study, a snowball sampling design was used, where two coders read 440 documents, of which 58 became cited references. The results of the analysis showed that among menthol smokers, higher intensities of

menthol, minty flavor and tobacco flavor all contributed to higher perceptions of strength, while among nonmenthol smokers, strength was determined primarily by the sensation of throat impact and tobacco flavor (Kreslake, Wayne & Connolly, 2008). Analysis of the articles found that the concentration of menthol was a major factor in determining consumer liking, and a product that has a moderate to high menthol taste will usually be rejected by menthol starters, while the same level will be quite acceptable to established menthol smokers (Kreslake et al., 2008). The body of evidence obtained from the 58 cited documents revealed that smokers who choose menthol have distinctly different sensory needs and approaches to cigarette smoking. Individuals who find the physical sensation of smoking uncomfortable may find an acceptable alternative in mentholated cigarettes (Kreslake et al., 2008). In this regard, menthol in cigarettes is being used to reduce negative sensory characteristics that many individuals associate with smoking, and could in turn discourage smoking cessation.

On September 22, 2009, the FDA prohibited cigarette manufacturers from adding artificial or natural flavors other than tobacco or menthol to cigarettes. The popularity of menthol arises from its minty flavor, aroma and sensory effects on the smoker. There are some menthol smokers that seek out the minty flavor and associated cooling sensation, while other menthol smokers seek to reduce the harshness and irritation associated with non-mentholated cigarettes (Yerger & McCandless, 2011).

In the article, *Menthol sensory qualities and smoking topography: a review of tobacco industry documents* written by Yerger and McCandless, 2011 tobacco industry documents were analyzed to determine the effects of the sensory qualities of menthol on smoking topography and the implications for public health. In a snowball sample design, a final collection of 252 documents was analyzed, of which 37 were cited throughout the article. Four key menthol taste

effects that appeals to smokers are cooling, clean/antiseptic, numbing/anesthetic and refreshing. It was also noted that menthol causes a sensation in which menthol taste and cooling are often times indistinguishable (Yerger & McCandless, 2011). Sensory cues contribute to how a cigarette is smoked, and the sensory effect of menthol is one of many factors that influence the smoking behavior of cigarette users. Menthol smokers are differentiated from other smokers by their desire for reduced irritation or by their desire for menthol taste. These menthol sensory properties make it easier for new smokers to consume cigarettes and more difficult for established smokers to quit, due to the absence of the irritation often perceived by nonmenthol cigarette users (Yerger & McCandless, 2011). The analysis of the documents showed that tobacco companies understand menthol's crucial role in making cigarettes easier to smoke, even in cigarettes with such low levels of menthol that they may be undetectable. The authors stated that banning the addition of menthol to cigarettes would have a positive impact on smokers of non-mentholated cigarettes as well as smokers of mentholated cigarettes in terms of encouraging smoking cessation and reducing smoke uptake (Yerger & McCandless, 2011).

Overall, certain evidence has been cited that smokers who choose menthol have distinctly different sensory needs and approaches to cigarette smoking. Individuals who find the physical sensation of smoking uncomfortable may find an acceptable alternative in mentholated cigarettes. In this regard, menthol in cigarettes is being used to reduce negative sensory characteristics that many individuals associate with smoking and could in turn discourage smoking cessation (Kreslake et al., 2008). The articles cited are divided as to how much menthol present in a cigarette affects the sensory outcomes for smokers, but overall agree that menthol even in low levels masks the harshness of tobacco and alleviates irritation associated with nicotine.

Menthol versus Nonmenthol Cessation Outcomes

On June 22, 2009, the Food and Drug Administration was granted the authority to regulate tobacco products by establishing the Center for Tobacco Products. Through this organization, the Food and Drug Administration will review evidence on the impact of menthol in cigarettes on public health to determine whether to recommend removal of mentholated cigarettes from the US market (Levy, Blackman, Tauras, Chaloupka, Villanti, Niaura, Vallone & Abrams, 2011). A study found that 39% of smokers would quit smoking if menthol cigarettes were banned, indicating to researchers that some smokers would quit rather than switch cigarette type if menthol was no longer on the market (D'Silva, Boyle, Lien, Rode & Okuyemi, 2012). The fact that few studies have explored the impact of menthol cigarette use on smoking cessation leads to the research question: Are menthol cigarette users more likely to quit using NRT treatment than non-menthol cigarette users using NRT treatment?

There are several NRT treatment options available to smokers interested in quitting which include dermal patches, lozenges, gum, nasal spray and inhalers. Besides these pharmacologic products, there are several other counseling services available to the public such as telephone quitlines. In a study conducted by D'Silva et al., 2012 entitled *Cessation Outcomes Among Treatment Seeking Menthol and Nonmenthol Smokers,* evidence was gathered to compare baseline characteristics and cessation outcomes of menthol and nonmenthol smokers who were seeking treatment through a telephone quitline. The study was conducted due to the fact that across the United States quitlines remain severely underutilized. The primary objective was to compare menthol and nonmenthol smokers calling into the quitline.

Participants were cigarette smokers who called the quitline between September 2009 and July 2011. Of those 6,257 participants who called in, only 715 smokers responded to the survey.

These responses were then used to compare treatment effectiveness for menthol versus nonmenthol smokers (D'Silvia et al., 2012). Logistic regression analyses were conducted to test menthol status as a predictor of 30-day point prevalence while controlling for other covariates, such as race, gender and age. Menthol smokers who called the quitline were more likely to be female, younger (18-24) and African American compared to nonmenthol smokers. Overall, 92.2% of menthol smokers and 94.8% of nonmenthol smokers enrolled to receive services following program registration, yet only 83.3% of menthol smokers that enrolled requested and were given some form of NRT (gum, patch or lozenge), compared to 86.7% of nonmenthol smokers (D'Silvia et al., 2012).

After looking at both responder and intent-to-treat analyses, researchers concluded that there was no significant difference in cessation outcomes reported between menthol and nonmenthol smokers. The odds of quitting for menthol smokers were not significantly different than nonmenthol smokers after controlling for other covariates (D'Silva et al., 2012). The results suggest that quitlines do engage a high proportion of menthol smokers who call, and that overall menthol smokers achieve abstinence rates comparable to nonmenthol smokers despite being less likely to request/receive NRT treatment. There are several limitations of this study which include, results that were self-reported, there was no biochemical verification of abstinence and 40% of the sample did not respond to the follow up survey. Yet the findings show that fewer menthol smokers are asking for and receiving medication, which could help implement future research in the area of menthol cessation success (D'Silva et al., 2012).

As noted previously in the article, *Cessation Outcomes Among Treatment Seeking Menthol and Nonmenthol Smokers*, menthol smokers tended to be younger (18-24), female and African American (D'Silva et al., 2012). Researchers Alexander, Crawford and Mendiondo,

2010 noticed this demographic correlation between menthol cigarette smokers and became interested in examining the relationship among occupational status, menthol smoking preference and employer sponsored smoking cessation programs and policies on quitting in an article titled, *Occupational status, work-site cessation programs and policies and menthol smoking on quitting behaviors of US smokers*. Researchers of this study expected that menthol smokers would experience fewer quit attempts, have less access to smoking cessation programs at work, and be less likely to work where there are smoking bans.

The data used for this analysis were obtained from the 2006/2007 Tobacco Use Supplement to Current Population Survey. Eligible respondents included those who were current smokers aged 18 years or older. The total sample size was 30,176 respondents. The demographics in this study were age, education, marital status, race/ethnicity, sex, region and smoking status. The variable occupation statuses were defined using three categories: blue-collar (farming, fishing, construction, transportation, production), white collar (management, business and finance, professionals) and service (restaurants/bars, casinos). Multiple logistic regression analyses controlling for age, race, sex, education and region were performed. The results showed that menthol smokers were younger, more often from the northeast region and service workers compared with nonmenthol smokers. Menthol smokers also had a higher rate of attempting to quit in the past 12 months (55%) versus nonmenthol smokers (50%) (Alexander, Crawford & Mendiondo, 2010). Results also showed that employees who did not have sponsored smoking cessation programs in place were less likely to quit smoking for one day or longer when compared to employees that had cessation programs in place. After controlling for race, gender and education, researchers found that there was no statistically significant difference for menthol and nonmenthol smokers on quitting. Although menthol versus nonmenthol smoking as a factor

did not show an influence on quitting, quitting behaviors were influenced by occupational class (Alexander, Crawford & Mendiondo, 2010). The study may have implications for service industry smokers, who were found to be younger and female, were exposed the most to second hand smoke, and had fewer employee cessation programs in place.

A limitation of the study is in the measure of quitting used in the analyses. Overall, the research showed that there was no difference in quit attempts between menthol and nonmenthol smokers, but there were differences in occupation status, where service workers, who tended to be female and younger, smoked menthol cigarettes more often and had lower quit rates than other occupations. This finding is consistent with other research that showed menthol cigarettes were being targeted to certain population demographics and what population may benefit if menthol were banned from being used in cigarettes (Alexander, Crawford & Mendiondo, 2010).

There has been debate among researchers as to whether or not menthol negatively impacts cessation among smokers. Recent research suggests that smoking menthol cigarettes negatively influences smoking cessation, while other studies show no difference between menthol and nonmenthol quit rates over a 6 month period, but results were not consistent across all follow up points. In the article *Quit Attempts and Quit Rates Among Menthol and Nonmenthol Smokers in the United State*, written by Levy et al., 2011, a large national and state-representative data set was used to examine quit rates among menthol and nonmenthol cigarette smokers. The study is unique in that it explicitly considers the role of quit attempts and also controls for the state tobacco control policies. Researchers used a logistic regression analysis to examine quitting behaviors from two waves of the Tobacco Use Supplement, one from 2003 and one from 2007. The sample was limited to self-respondents aged 18 years and older, which produced a sample size of 34,260 in 2003 and 31,250 in 2007.

Participants where then categorized into current smokers those who smoked at least 100 cigarettes in their lifetime and former smokers who had smoked at least 100 cigarettes in their lifetime but did not currently smoke. The former smokers were broken down into further sub-categories: recent quitters (those who had quit in the past year), and long term quitters who had quit in the past five years. All participants were classified into menthol, nonmenthol or no usual type (Levy et al., 2011).

Researchers created variables from the Tobacco Use Supplement to control for sociodemographic characteristics that could influence cessation behaviors which included: race/ethnicity, age, gender, marital status, educational attainment and household income. Data related to tobacco control policies included state level tobacco control expenditures, state cigarette prices and state level smoke free laws. The results of the pooled data showed that menthol smokers had a higher rate of quit attempts during the past year compared to nonmenthol smokers, yet menthol smokers compared to nonmenthol smokers were 4% less likely to have quit successfully in the past year in 2003 and 12% less likely in 2007 (Levy et al., 2011). The analysis of the data also indicated that the likelihood of a quit attempt in the past year was higher among women, Hispanic, non-Hispanic Black and younger smokers (18-24 years). From this data, a pattern was seen that indicated the quit attempt rate for menthol smokers was higher in non-Hispanic blacks compared to other racial groups, and for those smokers aged 18 to 24 compared to older aged smokers. Furthermore, the likelihood of quitting for menthol smokers was about 3.5% lower for those who quit in the past year and 6% lower for those who quit within the past 5 years when compared to nonmenthol smokers. The success rate of quitting was further reduced for non-Hispanic Blacks and those aged 18 to 24 within the past 5 years among menthol smokers (Levy et. al, 2011).

Overall, the results from this study indicate that menthol smokers are not less motivated to quit, as seen by their increased tendency to make a quit attempt compared to nonmenthol smokers, but are unsuccessful in maintaining smoking abstinence (Levy et al., 2011). The fact that menthol smokers were less likely to be successful in their quit attempts suggests that banning menthol in cigarettes may prompt existing menthol smokers to quit, who may otherwise not be motivated due to their strong loyalty to their menthol preference, as seen in a study where menthol users were less sensitive to price fluctuations than nonmenthol users. These results show that menthol is not merely an additive to cigarettes that caters to a flavor preference, but suggests it is more difficult for menthol smokers who want to quit smoking to stop smoking compared to nonmenthol cigarette users.

After analyzing several articles on cessation outcomes for menthol versus nonmenthol smokers, there seems to be a correlation between the demographic that menthol cigarettes cater to and success of quit attempts. In the article *Racial/ethnic differences in menthol cigarette smoking, population quit ratios and utilization of evidence based tobacco cessation treatment*, written by Stahre, Okuyemi, Joseph and Fu, 2010 the relationship between menthol cigarette smoking and the population quit ratio was examined and whether menthol smokers differed in utilization of evidence-based smoking cessation aids.

In a 2010 survey, 69% of African Americans reported that they smoked menthol cigarettes, compared with 23% of white smokers and 29% of Hispanic smokers. Add this to the fact that previous research has shown that African American smokers are less likely to quit smoking, it has been suggested that the relationship between menthol cigarettes and African Americans is a possible contributor to the observed differences in tobacco cessation outcomes between African Americans and Whites (Stahre et al., 2010). The aim of the study was to look

specifically at whether menthol smokers differed in utilization of evidence-based smoking cessation aids, while controlling for several demographic and smoking characteristics among a nationally representative sample of US adult smokers (Stahre et al., 2010). The study used data from the 2005 National Health Interview Study, resulting in a sample of 31,428 people aged 18 years or older of current and former smokers. Current and former smokers were asked if their usual brand was mentholated to determine menthol cigarette use. Approximately 26% of current smokers had used menthol cigarettes and 22% of former smokers used menthol. Multiple logistic regression analyses showed an association between menthol cigarette use and the population quit ratio and the utilization of quit aids, controlling for significant demographic and smoking characteristic variables.

Results of the study showed that African Americans reported a higher prevalence of menthol smoking compared with other racial groups, and additionally 49% of African American smokers reported a quit attempt in the previous year versus 41% of white smokers (Stahre et al., 2010). When examining the quit ratio by menthol status and race there was no significant difference found between the quit ratios for menthol versus nonmenthol smokers for whites (52% versus 50%, respectively), but there was an observed lower quit ratio for menthol versus nonmenthol smokers for African Americans (34% versus 49%). Thus the data indicated that African American menthol smokers were significantly less likely than white nonmenthol smokers to have quit smoking (Stahre et al., 2010).

When analyzing the data for utilization of quit aids, approximately 27% of current smokers who tried to quit in the past year and 22% of past-year former smokers used some form of NRT to help them quit. The most common NRT was the nicotine patch, and the overall odds of using any type of quit aid did not differ significantly between menthol or nonmenthol smokers

after controlling for demographic and smoking characteristics. After examining the data, researchers did note that African American current smokers had significantly lower odds of utilizing quit aids than white current smokers (Stahre et al., 2010).

The limitations of this study included self-reported measures for menthol cigarette use and use of quit aids which may lead to misclassification. Overall, the researchers in this article found that race significantly modified the effect of menthol cigarette smoking on smoking cessation as measured by the population quit ratio (Stahre et al., 2010). Among menthol smokers who are African American there is a decreased likelihood of smoking cessation, yet no significant decrease in likelihood of smoking cessation among white or Asian menthol smokers. These findings provide support of future research that could indicate a negative impact of menthol smoking on cessation in racial and ethnic minorities, particularly African Americans.

After review of four studies concerning menthol smokers and the effect that menthol has on cessation outcomes, a pattern has been observed. There are discrepancies on whether menthol in cigarettes has an effect on cessation outcomes, as Alexander et al., 2010 and D'Silva et al., 2012 found no significant difference between cessation outcomes in menthol versus nonmenthol smokers. However, Levy et al.,2011 and Stahre et al.,2010 found evidence through their research that indicated there was statistically significant evidence that indicated menthol smokers do in fact have a decreased likelihood of successful cessation outcomes compared to nonmenthol smokers. One point that was clear throughout all four studies was the fact that menthol smokers were motivated to quit, even more so at times than nonmenthol smokers, and that there were no differences noted between utilization of quit aids between menthol and nonmenthol smokers. What Levy et al.,2011 and Stahre et al., 2010 did find in their analyses was that African Americans have a significantly lower quit ratio among menthol versus nonmenthol smokers.

This indicates that further research needs to be conducted in the area of menthol cessation outcomes in smokers by race and why there are discrepancies seen between cessation outcomes in menthol white smokers and menthol African American smokers. The research that has been reviewed supports the idea that menthol smokers are as motivated to quit smoking as nonmenthol smokers, and that menthol smokers do utilize quit aids as frequently as nonmenthol smokers. The research question as to whether menthol cigarette users are more likely to quit using NRT treatment than non-menthol cigarette users using NRT treatment could be further broken down to analyze the differences seen between African American menthol smokers and cessation outcomes compared to menthol smokers of other ethnicities and their cessation outcomes.

Research Design and Methods

This secondary data analysis of the study *Bitter Taste Phenotype and Oral NRT Adherence*, cross over design with randomized order of NRT treatment type evaluated the relationship between menthol cigarette sensory response and cessation rates through usage of nicotine replacement therapy (NRT) versus non-menthol cigarette users.

Specific Aims:

1. Are menthol cigarette users more likely to quit using NRT treatment than non-menthol cigarette users using NRT treatment in a two-week study?
2. What is the relationship between cigarette smoking and NRT usage regarding sensory perception in the categories of liking, satisfaction and sensation strength?
3. Is there a difference in the sensory perception of liking, satisfaction and sensation strength between menthol and non-menthol cigarette smokers?

Design

A crossover experimental design (Figure 1) was implemented to address the above aims of this project. Participants were randomly assigned to order of oral NRT product with 50% of participants experiencing one week of nicotine lozenge followed by one week of nicotine inhaler and the other 50% of participants experiencing the reverse. This was a secondary data analysis of the study *Bitter Taste Phenotype and Oral NRT Adherence.*

Week 1	**Week 2**	
Inhaler	Lozenge	**n=55**
Lozenge	Inhaler	**n=65**

Note: Randomized to order of treatment; Protocol conducted in CCTS Clinical Research Center
Figure 1. Cross over design of NRT treatment type

Sample size justification

Sample sizes for the experiment were determined based on the average usage of 4.5 nicotine cartridges per day with a standard deviation of 2.1 cartridges per day and an average usage of 7.7 lozenges per day with a standard deviation of 3.2 lozenges per day. Assuming a correlation of 0.7 between lozenge and inhaler usage by participants there would need to be 54 individuals in each group. An additional 8 participants per group were enrolled to yield 62 participants per group and a final sample of 124. Four participants dropped out from the study for a final sample of 120 participants.

Inclusion Criteria

Inclusion criteria were being between the age of 18 through 55, cigarette smoker for at least one year and a minimum of 10 cigarettes/day, willing to quit cigarette smoking for two weeks, not pregnant or lactating, no oral or nasal disease, no prescribed medications that may alter taste, no significant chronic or acute medical or psychiatric illnesses, no current drug abuse diagnosis,

have not tried to stop smoking using NRT in the past three months, no contraindications to either of the two NRT products and no other household members enrolled in the study.

Recruitment

Advertisements were placed in free neighborhood weekly newspapers distributed to residents, as well as fliers placed in Ohio State University clinics. Flyer placement in worksites was also used.

Procedure

A trained staff member telephoned each interested person to determine eligibility based on inclusion and exclusion criteria. A nurse practitioner on the study team conducted a baseline history and physical examination. The project nurse completed a baseline face-to-face visit focused on contraindications to NRT as well as a face-to-face visit at the end of week 1 and 2 as outpatients in the Ohio State University Clinical Research Center. Participants were asked to record at home their NRT intake recorded on a daily log, sensory response based on the Duke Sensory Scale and recorded the number of times they slipped up and smoked. At each face-to-face visit saliva samples were collected for cotinine assay, and exhaled carbon monoxide to determine smoking status. The OSU Biomedical IRB approved the research.

Protocol

NRT was provided at no cost to the participant as part of the research protocol. At baseline the project nurse provided instructions on the randomly assigned oral NRT product and distributed a 1-week supply of the relevant NRT. Participants were paid $100 at the end of week 1 and 2 as well as being compensated for parking.

Measures

NRT Sensory Response is measured using the Duke Sensory Scale (Westman, Behm & Rose, 1995) instrument to obtain participants sensory experience of each oral NRT product. The 7

point scale ranges from not at all (1) to extremely (7) based on three dimensions of liking, satisfaction and strength in five areas (mouth, nose, throat, chest, windpipe). This was reported daily by participants on Teleform® log.

NRT Adherence was recorded by the number of lozenges or inhaler cartridges per day in a daily log kept by participants at home based on the respective week.

Fagerström Test for Nicotine Dependence was measured at baseline. The 6 item instrument has 4 dichotomous responses with potential score range of 0 to 10 with a higher score indicating greater dependence (>6 classified as high dependence).

Measure of Smoking Status- Carbon Monoxide in Exhaled Air

Carbon monoxide was measured at baseline and weekly to validate short-term nonsmoking status during NRT treatment. An exhaled CO level <8 indicates that the participant is a non-smoker/smoking abstinence, while a CO level >8 indicates that the participant is a smoker/relapser.

Data Analysis

Aim 1 was a descriptive analysis about proportion of quitting and continuing smoking comparing menthol and nonmenthol smokers after week 1 and 2. Aim 2 was a correlation analysis (2-tailed) looking at how cigarette smoking and NRT usage was related to sensory perceptions. Aim 3 used a one-way ANOVA to determine if the two groups of menthol and nonmenthol cigarette smokers were different in their sensory perceptions of liking, satisfaction and sensation strength.

Findings

A total of 120 cigarette smokers participated in this study and selected sample characteristics are detailed in Table 1

Age (yrs)	32.1 ± 10.3
Female	47.5%
Male	52.5%
White	65.8%
African American	27.5%
Cigarettes/day	15.4 ± 5.7
Menthol	40.3%
Education ≤ H.S.	36.7%
Income ≤ $15,000	48.3%

Table 1. Sociodemographic and smoking characteristics (N=120)

Aim 1 focused on analyzing which group, nonmenthol or menthol smokers, were more likely to quit during a two-week trial using NRT treatment. Results showed that among those who quit after week 1 there were more nonmenthol cigarette smokers compared to menthol cigarette smokers and comparable results were seen in week 2. Table 2 shows the break down in smoking status between the two groups.

Week 1	Nonmenthol	Menthol
Quit Smoking	60.9%	39.1%
Continued Smoking	59.7%	40.3%
Week 2	Nonmenthol	Menthol
Quit Smoking	53.8%	46.2%
Continued Smoking	64.5%	35.9%

Table 2. Comparison of smoking status by menthol/nonmenthol cigarette use

Aim 2 analyzed the relationship between NRT usage and cigarette smoking regarding the sensory perceptions of liking, satisfaction and sensation strength. The following Table 3 represents the average sensory, liking and satisfaction responses to the NRT lozenge and inhaler. The results showed the higher baseline cigarettes per day seen, the higher the liking score of using the lozenge as a form of NRT. There was a positive relationship between lozenge usage and liking of lozenge score. Satisfaction with lozenges related to liking the lozenge as a form of NRT. Satisfaction with the NRT inhaler positively related to its sensory properties and increased liking of the inhaler showed an increased liking of the lozenge as a form of NRT. Consequently if you are satisfied with the lozenge as a form of NRT results showed that you will be satisfied with the inhaler as well and vice versa. The data indicate that there is no specific preference noted in NRT usage between inhaler or lozenge in the categories of liking, satisfaction or sensation strength but there was an increased liking of the lozenge if you smoked more cigarettes per day at baseline. In the chart grayed out sections show categorical data that has already been previously stated elsewhere in Table 2 or is data that does not relate to one another such as inhaler/day and sensory lozenge perceptions.

	Smoke/day	Loz /day	Inhaler /day	Sensory Inhaler	Sensory Loz	Liking Inhaler	Liking Loz	Satsf. Inhaler	Satsf. Loz
Baseline Cig/ Day									
Loz/ Day	r=0.029 N=117								
Inhaler/ Day	r=0.137 N=119								
Sensory Inhaler	r= 0.038 N= 94		r=0.084 N=94						
Sensory Loz	r=0.037 N=89	r=0.081 N=87							
Liking Inhaler	r=0.065 N=98		r=0.049 N=98	r=0.083 N=94					

Liking Loz	r=-0.162* N=92	r=0.146* N=91			r=0.013 N=81				
Satisf. Inhaler	r=0.40 N=97		r=0.012 N=97	r=0.219* N=93		r=0.709* N=97			
Satsf. Loz	r=-0.064 N=92	r=0.096 N=91			r=0.076 N=91		r=0.538* N=92		

Note: *= $p < 0.05$; Significant at the $p < 0.05$ level

Table 3. Correlations of NRT usage and sensory, liking, and satisfaction responses to each NRT product

Aim 3 further broke down the outcomes in sensory perceptions in the categories of liking, satisfaction and sensation strength and looked at the differences seen between nonmenthol and menthol cigarette smokers. Results outlined in Table 4 showed that menthol smokers had a significantly increased sensory response to the NRT lozenge compared to that of nonmenthol smokers. The mean average sensory response score of the lozenge and inhaler showed that nonmenthol smokers do not respond as much to the sensory aspect of the lozenge. In the data there were two versions of sensory where sensory 2 in Table 4 relates to 3 locations tested for sensory response in participants. The average sensory response in Table 4 shows the sensory response of participants in 5 locations.

	Nonmenthol	Menthol	Significance between groups
Average sensory inhaler	n= 53 14.26 ± 5.294	n=40 16.19 ± 6.878	.129
Average sensory lozenge	n=48 14.08 ± 4.349	n=40 16.99 ± 5.423	.006*
Average sensory inhaler 2	n=71 14.4927 ± 5.343	n=47 16.3909 ± 6.833	.094
Average sensory lozenge 2	n=71 14.61± 5.437	n=47 17.6551 ± 5.951	.005*
Average liking of inhaler	n=54 3.76 ± 1.538	n=43 3.71 ± 1.795	.885
Average liking of lozenge	n=55 2.50 ± 1.326	n=36 2.94 ± 1.911	.190

Average satisfaction of inhaler	n=54 3.60 ± 1.478	n=42 3.79 ± 1.663	.552
Average satisfaction of lozenge	n= 55 3.21 ± 1.408	n= 36 3.77 ± 1.807	.102

Note: *= $p < 0.05$; Significant at the $p < 0.05$ level

Table 4. Comparison of sensory, liking and satisfaction to NRT products by menthol/nonmenthol cigarette smokers Mean ± SD

Discussion

Few research studies have explored the impact of menthol cigarette use on smoking cessation solely focusing on quit rates between menthol and nonmenthol smokers while controlling for other co-variables. The literature review conducted analyzed four research studies that compared menthol and nonmenthol cessation outcomes but only one study conducted by Levy et al., 2011 focused primarily on quit rates on a national level disregarding other variables that researchers tend to analyze with smoking cessation such as NRT treatment type (quitlines), occupational status and race.

In the current study, aim 1 compared whether menthol or nonmenthol cigarette smokers were more likely to quit using NRT treatment in a two week study. Results showed that menthol smokers were less likely to quit (39.1%) than nonmenthol smokers (60.9%) during week 1 of treatment with similar results collected at the end of week 2. The results seen during the two week study were different than the literature analyzed in Stahre et al., 2010, D'Silva et al., 2012 and Alexander, Crawford and Mendiondo, 2010 with similar results found where menthol smokers had a lower quit rate in research conducted by Levy et al., 2011.In contrast, Stahre et al., 2010 looked at whether menthol smokers differed in their utilization of evidence-based practice smoking cessation aids and found that there was no significant difference found between the quit ratio for menthol smokers (52%) versus nonmenthol smokers (50%). Although Stahre et al., 2010 findings showed that menthol smokers utilize cessation aids, D'Silva et al., 2012 found

that only 83.3% of menthol smokers who called into a quitline requested some form of NRT compared to 86.7% of nonmenthol smokers calling into the quitline. D'Silva et al., 2012 found similar results to Stahre et al., 2010 where the odds between quitting between the two groups were not statistically significant. In addition, menthol smokers were less likely to request/ receive NRT, this holds important significance to future studies as to why menthol smokers are not utilizing NRT treatment when results show smoking cessation pharmacotherapy yields a 2 to 3 yield improvement in quitting success. Alexander, Crawford and Mendiondo, 2010 also found that menthol smokers had a higher quit attempts in the past 12 months (55%) compared to nonmenthol smokers (50%) indicating the motivation seen in this smoking group. This supports results found in our study and from the study conducted by Levy et al., 2011 that showed menthol smokers being 4% less likely to quit successfully in the past year in 2003 and 12% less likely to be successful in cessation outcomes in 2007. More studies need to be conducted that focus on menthol cigarette use and the impact on cessation outcomes while controlling for other variables.

Owing to its physiological effects, menthol contributes to the sensory qualities of cigarette smoke and affects smoking topography and cigarette preference (Yerger & McCandless, 2011). The data collected in this study found that there was no specific preference noted in the categories of sensation strength, liking and satisfaction between NRT treatment type and cigarette usage except in increased baseline cigarettes per day, which correlated to an increased liking of the NRT lozenge. When further breaking down aim 2 to look specifically at menthol versus nonmenthol sensory responses to sensation strength, liking and satisfaction results indicated that menthol cigarette smokers had an increased sensory response to the NRT lozenge compared to nonmenthol smokers.

These findings differ from the data found in the literature review, due to the nature of what sensory response was being measured. In our study we focused on the sensory perceptions of the NRT treatment, while in the literature review the studies focused on the sensory perceptions of liking, satisfaction and sensation strength based on the amount of menthol present in cigarettes. This discrepancy seen in data collection and the literature review is due in part that few studies have examined the impact smoking menthol cigarettes has on NRT treatment.

The literature review did show that all four of the studies analyzed agree that menthol even in low levels masks the harshness of tobacco and alleviates irritation associated with nicotine. Yerger and McCandless, 2011 found that menthol smokers are differentiated from other smokers by their desire for reduced irritation or desire for menthol taste. This shows that menthol smokers have distinctly different sensory needs which supports the data that found that menthol smokers had a distinct sensory response to the NRT lozenge compared to nonmenthol cigarette smokers. Kreslake, Wayne and Connolly, 2008 also found that nonmenthol smoker's sensory perceptions were determined based off the strength of throat impact and tobacco flavor versus menthol smokers whose sensory perceptions were determined based on the concentration of menthol present in the cigarette not the tobacco/nicotine content. Yerger, 2011 showed that small concentrations of menthol were more effective than large concentrations and that menthol even in low levels masks the harshness associated with nicotine.

More literature needs to be produced examining the effects that menthol cigarette smoking has on NRT treatment type, as the literature does show that menthol smokers have unique sensory needs and treatment should take these findings to individualize care so menthol smokers can be more successful in long term cessation outcomes.

Conclusion

The effects of mentholation in cigarettes are an important issue today. With over 10 million menthol cigarette smokers in the United States in 2008, the fact that few studies have explored the impact of menthol cigarette use on smoking cessation products in large population based studies is alarming, especially when recent research has suggested that smoking menthol cigarettes negatively impacts cessation outcomes in adults (Levy et al., 2011). The significant correlation seen between menthol cigarette smokers and increased sensory perception to NRT lozenges can be used to better understand factors that influence long term cessation outcomes. Menthol cigarette smokers have been shown through the literature to have unique sensory perceptions and further research examining these sensory responses could help cessation pharmacotherapy treatment in the future cater to this population. The overall odds of using any cessation aid did not differ significantly between menthol and nonmenthol smokers after controlling for demographics and smoking characteristics as seen in the data and by the study conducted by Malarcher et al., 2011, but the sensory perceptions of NRT usage showed that menthol smokers had an increased positive sensory response to the NRT lozenge which could help improve cessation outcomes.

This study shows the gaps in research conducted on the sensory perceptions in the categories of liking, satisfaction and sensation strength through NRT usage and the importance of continued research in this area to bridge the gaps seen in cessation outcomes between menthol and nonmenthol smokers.

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